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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO.   |
|---|-------------|----------------------|------------------------------|--------------------|
| 09/365,677  | 08/02/1999  | PING KUEN LAM        | 021234-1.00                  | 2089               |
| 20350   | 7590        | 09/24/2003           |                              |                    |
| TOWNSEND AND TOWNSEND AND CREW, LLP<br>TWO EMBARCADERO CENTER<br>EIGHTH FLOOR<br>SAN FRANCISCO, CA 94111-3834 |             |                      | EXAMINER<br>FALK, ANNE MARIE |                    |
|   |             |                      | ART UNIT<br>1632             | PAPER NUMBER<br>18 |
|   |             |                      | DATE MAILED: 09/24/2003      |                    |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                    |                  |
|------------------------------|------------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.                    | Applicant(s)     |
|                              | 09/365,677                         | LAM ET AL.       |
|                              | Examiner<br>Anne-Marie Falk, Ph.D. | Art Unit<br>1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 July 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 4-6,8-13,15,17,18,20,22-25 and 27-33 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 4-6,8-13,15,17,18,20,22-25 and 31-33 is/are allowed.
- 6) Claim(s) 27-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 October 2002 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

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### **DETAILED ACTION**

The amendment filed July 3, 2003 (Paper No. 17; hereinafter referred to as "the response") has been entered. Claims 4, 8, 11, 15, 17, 20, and 27-30 have been amended. Claims 1-3, 19, 21, and 26 have been cancelled. Claims 31-33 have been newly added.

Accordingly, Claims 4-6, 8-13, 15, 17, 18, 20, 22-25, and 27-33 are pending in the instant application.

The following rejections are reiterated and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

#### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 3, 2003 (Paper No. 17) has been entered.

The rejection of Claims 1-6, 8-13, 15, and 17-30 under 35 U.S.C. 103(a) is withdrawn in view of Applicants' arguments at pages 14-22 of the response. In particular, Applicants argue that none of the cited references employ a keratinocyte layer over a fibroblast layer on the same side of a biosynthetic substratum and that such an arrangement would not be obvious. This argument is found to be persuasive.

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***Specification***

The amendment filed June 13, 2002 (Paper No. 10) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment designated **amendment D**.

Numerous amendments rely on subject matter that is not included in the specification. Applicants have not pointed to appropriate support for these amendments **within the specification**.

Applicant is required to cancel the new matter in the reply to this Office Action.

With regard to amendment D of the specification, the amendment filed July 3, 2003 (Paper No. 17) replaces the first paragraph of the amendment filed June 13, 2002 (Paper No. 10), but Applicant was required to delete the entire new section added in the June 13, 2002 amendment D (7 paragraphs).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***New Matter***

Claims 27-30 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27-30 have been amended to recite the new limitation "wherein the membrane has holes capable of draining exudate" instead of the limitation "wherein the membrane has microholes of about 40  $\mu\text{m}$  diameter."

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At page 13 of the response, Applicants state that support for this subject matter is found in the specification in the legend of Figure 1A and that the figure itself shows such holes. However, the specification does not refer to holes and the figure does not show holes.

### ***Conclusion***

Claims 4-6, 8-13, 15, 17, 18, 20, 22-25, and 31-33 are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b): Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.



PRIMARY EXAMINER

ANNE-MARIE FALK, PH.D.

PRIMARY EXAMINER